REMARKS

Dealing with preliminary matters first, Applicants thank the Examiner for acknowledging the claim to priority and receipt of the priority document.

In the present Amendment, claim 1 has been amended herein to incorporate the subject matter of claim 3. Accordingly, claim 3 has been canceled, and claims 4 and 5 have been amended to depend from claim 1.

Claim 5 has been further amended for purposes of clarity.

No new matter has been added, and entry of the Amendment is respectfully requested. Upon entry of the Amendment, claims 1, 2 and 4-14 will be pending.

Referring to page 3 of the Office Action, claims 1-14 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Makovec, et al. (U.S. Patent No. 5,130,474) in view of Midler, et al. (U.S. Patent No. 5,314,506). Applicants traverse and respectfully request the Examiner to reconsider in view of the amendment to the claims and the following remarks.

The presently recited crystallization method for the preparation of dexloxiglumide provides substantial advantages both in qualitative terms (rheological properties of the obtained product) and in quantitative terms (yield increase) with respect to the known method by Makovec.

These advantages would have been unexpected to a person of ordinary skill in the art at the time of the invention and, moreover, could not have been foreseen on the basis of the teachings and disclosure of Makovec.

a) Only through the presently claimed process has it become possible to obtain a crystalline product having the features recited in present product claims (that is, a product having

superior morphological and rheological properties, such as adequate flowability and high dissolution rate, which allow its use for the preparation of pharmaceutical products).

b) A simple crystallization employing isopropyl ether (which, Applicants submit, does not constitute the state of the art), without using the presently claimed method of adding a microcrystalline seeding with the defined particle size (D_{50}<20 μm), would provide a product having the same unfavorable rheological properties as the product obtained by crystallization employing EtOH-H_20, which is shown in FIGs. lB and 2B of the present application and is discussed in corresponding sections of the present specification.

c) A further advantage of the process of the invention is a substantial increase of the yield, which was 96 % in working Example 1 (see the first full paragraph on page 8 of the present specification). According to the process of Makovec, the compounds crystallized from ethanol-H_20 have a yield of 47.7 %. See Table 3 of Makovec between columns 5 and 6.

The presently claimed method, therefore, achieves a substantial increase in the yield as compared to the prior art method.

d) Further, Applicants submit herewith an unexecuted Declaration Under 37 C.F.R. § 1.132 of co-inventor Dr. Francesco Makovec, which supports the patentability of the present claimed subject matter. An executed version of the Declaration will follow shortly.

For comparison purposes, Dr. Francesco obtained the following analytical results relating to lot G3756-A according to the process of working Example 1 *without* the addition of the seeding material. According to the results obtained, the average particle size (D_{50}) for the obtained product was 15.025 μm, and the span index was 3.845. These results are distinguishable from those obtained by the presently claimed method, wherein the mean size

measurement (D_{50}) was 97.357, and the span index was 1.608. See the last full paragraph on page 8 of the present specification and Fig. 1A.

Moreover, Dr. Francesco asserts that these superior results would have been unexpected to a person of ordinary skill in the art at the time of the invention.

With regard Midler, in this reference the Authors describe a process that involves the use of fluid jet streams that achieve a high intensity micro mixing that allows one to obtain, in a single run, small particle size compounds having a diameter equal or less than 25 μm.

Therefore, the method of Midler allows the production of particles having the opposite characteristics of those described in the present patent application. The presently claimed method permits the production of crystalline dexloxiglumide having physical properties suitable for the preparation of pharmaceutical forms for oral use, namely a crystalline particle form having a percentage (by volume) of less than 15 % of fine particles (having dimension less than 10 μm), and an average particle size value (D_{50}) of between 50 and 130 μm, which features are presently recited in claim 6.

With respect to product claims 6-10, Applicants assert that the cited prior art does not disclose or suggest a product having the presently recited features. Accordingly, the presently claimed product is not only obtained by a patentable method of production, but also has a patentably distinguishable structure.

In view of the above, Applicants respectfully request reconsideration and withdrawal of the §103 rejection of claims 1-14 based on Makovec in view of Midler.

Reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be

best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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